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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/683,104	11/19/2001	Thomas C. Kienzle III	SUR3	8647

7590 09/30/2004

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EXAMINER

SHAW, SHAWNA JEANNINE

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/683,104

Applicant(s)

KIENZLE, THOMAS C.

Examiner

Shawna J. Shaw

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 9-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☒ Claim(s) 7 and 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 November 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 03262002.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group I (claims 1-8) in the reply filed on 7/14/2004 is acknowledged. The traversal is on the ground(s) that the search would not present a serious burden to the examiner because all claims are generally drawn to "a computer assisted surgery system" for orienting, locating, or inserting components within a body. This is not found persuasive because the groups are separately classified in distinct subclasses, have different scopes (e.g., total hip replacement surgery vs. any orthopedic procedure [0059-60], x-ray imaging vs. "an" imaging device) and contain divergent subject matter (e.g., invasive vs. non-invasive). The requirement is still deemed proper and is therefore made FINAL.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the x-ray imaging device, the "means for determining the location," and the "means for recording" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate

figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claim 1 is objected to because of the following informalities: Claim 1 is incomplete in that it is drawn to a *computer assisted* surgery system, however a computer has not been set forth in the body of the claim. In claim 1 line 14, it appears that "drill guide" should be changed to -instrument—because a drill guide is not introduced until claim 2. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear from the specification and drawings what *structure* or element(s) correspond to the "means for determining

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the location of one or more virtual trajectories" and "means for recording the pose of the drill guide at a signal from the surgeon."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Kienzle, III et al. '902.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claims 1-3, Kienzle, III et al. disclose a computer assisted surgery system including x-ray imaging device (112), display means (122), drill guide (128), localizing device (120), means for determining the location of one or more "virtual" trajectories (as shown by arrow representing desired insertion

point) with system controller (121), and means for superimposing the real (222, 223) and virtual (arrow) trajectories over a 2D image to direct guide pin insertion (fig. 14).

6. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Malackowski et al.

Malackowski et al. disclose display means (108) for displaying an x-ray acquired image [0056], a surgical instrument (114), localizing device (104), and means (2704, 2706) for superimposing real and "virtual" trajectories relative to one another over a 2D image of the body part (fig. 27).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-6 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kienzle, III et al. '902.

Regarding claims 4-6, Kienzle, III et al. does not explicitly address repeatedly inserting guide pins, however does set forth a procedure for visualizing the drill guide trajectory relative to an intramedullary rod having two insertion points (286) fixed and known relative to one another (fig. 18). It is therefore inherent that multiple guide pins are inserted by the procedure of Kienzle, III et al. at set distances. Alternatively, it would have been obvious at

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the time the invention was made to a person of ordinary skill in the art to position the drill guide based on the alignment of the desired, or virtual, trajectory with respect to a previously inserted guide pin so as to achieve the necessary spacing when inserting multiple guide pins such as between holes of an intramedullary rod.

7. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barrick in view of Cinquin et al.

Regarding claims 1-3, Barrick disclose a computer assisted surgery system including an x-ray imaging device (200), a computer (col. 4 line 66 – col. 5 line 2), a display (fig. 4), a drill guide (301), a localizing device (212) and means for superimposing a real trajectory over at least one 2D image (fig. 4). See also col. 5 lines 2-9. Barrick differs from the claimed invention only in that a virtual trajectory is not addressed. Cinquin et al. generally disclose that it is known to determine and superimpose a “virtual” trajectory with respect to a real trajectory (fig. 6) to direct insertion of a surgical instrument - wherein correct alignment is achieved when the two trajectories are congruent (i.e., having a difference signal of zero). See paragraphs [0068-70]. It would have been obvious at the time the invention was made to a person of ordinary skill in the art to determine and superimpose a “virtual”, or desired, trajectory as taught by Cinquin et al. with respect to the real trajectory of Barrick so as to position the drill guide with a higher degree of accuracy and to reduce the patient’s level of exposure to ionizing radiation (Cinquin et al. [0004], [0007-8]).

Allowable Subject Matter

8. Claims 7 and 8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ehnholm et al. (6,671,538) disclose localizing an instrument in an MR imaging device including superposing real and virtual trajectories relative to one another over a 2D image of a body part (fig. 3).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawna J. Shaw whose telephone number is (703) 308-2985. The examiner can normally be reached on 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Shawna J. Shaw
Primary Examiner
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09/28/2004